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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/832,273	04/10/2001	Roland Cherif-Cheikh	05339-014003	2832
37903	7590	02/23/2006	EXAMINER	
DAWN JANELLE AT BIOMEASURE INC. 27 MAPLE STREET MILFORD, MA 01757			LAM, ANN Y	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 02/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/832,273	<b>Applicant(s)</b> CHERIF-CHEIKH, ROLAND	
	<b>Examiner</b> Ann Y. Lam	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 6-8 and 22-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-8 and 22-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 1, 2005 has been entered.

### ***Claim Objections***

1. Claim 24 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 24 only recites "wherein the housing contains the liquid or semi-solid composition" and is dependent from claim 23, which recites the same limitations. Thus, claim 24 does not further limit claim 23.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 6-8 and 22-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6, line 12, recites "the plunger". It is not clear whether "the plunger" refers to "a plunger" in line 9, or "a septum plunger" in line 11. (Likewise, the terms "the plunger" in lines 14, 18, 21 and 22 of claim 6, as well as claim 8, line 2, claim 22, line 2, and claim 25, line 2, are vague because it is not clear whether "the plunger" refers to "a plunger" in line 9 or "a septum plunger" in line 11.) Applicant should use terms such as "first plunger" and "second plunger" to overcome this rejection. For examination purposes, the limitation "the plunger" in claim 6, line 12 (and subsequent lines and claims) are interpreted to refer to the plunger of line 9.

Claim 25 recites the limitation "the movement" in line 2. There is insufficient antecedent basis for this limitation in the claim. (The word "the" should be deleted.)

(Claims 7, 23, 24, 26, and 27 are rejected under 112, second paragraph, because they depend from one of the claims that are vague and indefinite as mentioned above.)

***Double Patenting***

3. Claims 6-8, 22-24 and 27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3 and 4 of U.S. Patent No. 5,695,463 in view of Scherer et al., 2,460,039.

Cherif-Cheikh '463 discloses the invention substantially as claimed (see claims 1, 3 and 4 of patent '463.) More specifically, patent '463 teaches:

a hollow housing (i.e., "main body member", in col. 4, line 4) capable of containing a combined liquid and a dry drug composition (col. 4, line 32);

a hollow needle (col. 4, line 4);

a plunger (col. 4, line 5);

a hollow sleeve (col. 4, line 8) slidably connected to the distal end of the housing and arranged to cover the needle prior to injection, to retract into the housing during injection and to cover the needle after the injection (col. 4, lines 8-17);

and wherein the device is designed such that when the sleeve is pressed against the subject, the sleeve retracts into the housing thereby allowing the needle to penetrate into the subject (col. 4, lines 10-13).

However, patent '463 does not teach a septum plunger slidably arranged within the housing between the plunger and the distal end of the housing, said septum plunger being configured to isolate the liquid and/or dry drug composition between the septum plunger and the distal end of the plunger; wherein the hollow sleeve contacts said septum plunger as said septum plunger is displaced by said plunger towards the distal

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end of the housing; and when the plunger is pushed into the housing, the proximal end of the needle pierces the septum plunger thereby exposing the proximal end of the needle to the previously isolated composition and the composition is pushed from the housing into and through the needle and into the subject.

However, Scherer et al. teach a syringe wherein the medicament is kept sterile until the syringe is put into use by providing a slidable piston (30) which seals and contains the medicament prior to use and puncture by a rear end of a double ended needle (34), (col. 1, lines 15-33).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a slidable piston and double ended needle as taught by Scherer et al. in place of the means to release the medicament (i.e., members 16 and 26) in the invention of patent '463 because Scherer et al. teaches that the configuration with the slidable piston and double ended needle provides the advantage of sealing the medicament and thereby maintaining sterility of the medicament prior to use. (The slidable piston taught by Scherer et al. is considered the claimed septum plunger.) Such modification of patent '463 in view of Scherer et al. permits the septum plunger to contact the sleeve of patent '463 as the septum plunger is displaced by the plunger towards the distal end of the housing; and when the plunger is pushed into the housing, the proximal end of the needle pierces the septum plunger thereby exposing the proximal end of the needle to the previously isolated composition, wherein the composition is pushed from the housing into and through the needle and into the subject (as claimed by Applicant). Also, as to claims 23 and 24, Scherer et al. teach

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that the housing contains the liquid composition (col. 1, line 16). As to claim 27, the septum plunger contains a bore (40) which the needle pierces the bore in the septum plunger during use of the injection device (see col. 3, lines 41-44, and see fig. 2 and 3).

As to the following claims, patent '463 teaches the limitations as follows.

As to claim 7, the proximal end of the housing comprises a flange (see claim 4 of '463).

As to claim 8, the proximal end of the plunger comprises a flange (see claim 3 of '463).

As to claim 22, the device is further configured such that when the composition is pushed out of the housing, the plunger moves the sleeve out of the housing to cover the needle (col. 4, line 15).

4. Claim 25 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,695,463 in view of Scherer et al., 2,460,039, as applied to claim 6 above, and further in view of Whitley, 5,399,170.

Cherif-Cheikh '463 in view of Scherer discloses the invention substantially as claimed (see above with respect to claim 6), except for a releasable lock to inhibit the movement of the plunger into the housing.

However, Whitley '170 discloses a syringe with a protective sheath, and further discloses a releasable lock in order to prevent movement of the plunger prior to use, (see column 3, lines 6-17). It would have been obvious to one of ordinary skill in the art

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at the time the invention was made to provide a releasable lock as taught by Whitley on the Cherif-Cheikh '463 syringe, as it would be desirable to prevent movement of the plunger prior to use.

5. Claim 26 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,695,463 in view of Scherer et al., 2,460,039, as applied to claim 6 above, and further in view of Hutson, 5,242,416.

Patent '463 in view of Scherer et al. teach the invention substantially as claimed (see above with respect to claim 6), except for a removable cap which covers the sleeve. Hutson however teaches this limitation.

Hutson discloses a syringe having a retractable sleeve (206) arranged to cover the needle. Hutson further discloses a cap (62 or 250) and teaches that the needle is protected by the cap (see column 8, lines 12-13) and that the cap may be placed on the sheath to protect the needle temporarily prior to additional use, where intermittent injections are required, for example, and the cap may be attached after use and the entire assembly may be disposed.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a removable cap as taught by Hutson on the sleeve of the syringe as taught by patent '463 in view of Scherer et al. because Hutson teaches that providing a cap on a sleeve (or sheath) protects the needle before, during or after use.



### ***Response to Arguments***

Applicant's arguments with respect to the above claims have been considered but are moot in view of the new ground(s) of rejection. (Applicant's amendment overcame the Tischlinger reference because the Tischlinger reference does not teach that the sleeve is capable of contacting a plunger as claimed by Applicant.)

Also, on page 4, Applicant objects to the finality of the previous Office action. Applicant submits that since the prior amendment did not "necessitate the new ground of rejection" and since no information disclosure statement was filed during the period set forth in 37 CFR 1.97(c), the finality of the action was premature. The Office maintains that the finality of the previous Office action was appropriate because the new amendments to the claims substantially changed the scope of the claims and thus required new search and consideration.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L. 